

**PHS Report Summarizes Current Scientific Knowledge on  
the Use of Post-Exposure Antiretroviral Therapy for Non-Occupational Exposures**

***Therapy Remains Unproven: Should Not be Used Routinely***

In recent years, the Public Health Service (PHS) has recommended the use of antiretroviral drugs to reduce the risk of occupational HIV transmission following workplace exposures (e.g., health care workers exposed through accidental needlesticks). Scientific studies have shown the drugs to be both safe and effective for this use. While this type of therapy is not 100% effective, it has been found to significantly reduce the risk of HIV infection among health care workers following percutaneous (through the skin) exposures.

Questions have arisen about whether similar therapy should be offered to people with unanticipated sexual or drug injection-related exposures to HIV. However, researchers do not know if findings among health care workers are applicable in other settings where therapy may not be initiated as quickly, where the HIV status of the source may not be known, where the regimen cannot be closely monitored, and where repeated exposures may occur. To consider these questions, PHS convened scientific experts from across the nation to review all available data. The September 25, 1998, issue of the *Morbidity and Mortality Weekly Report* summarizes the data considered and the outcomes of this consultation.

PHS has concluded that there are no conclusive data on the effectiveness of antiretroviral therapy in preventing HIV transmission after non-occupational exposures. It is therefore not possible to make definitive recommendations regarding its use.

***Because the therapy remains unproven and can pose risks, physicians should consider its use only in individual circumstances when the probability of HIV infection is high, the therapy can be initiated promptly, and adherence to the regimen is likely. It should not be used routinely and should never be considered a form of primary prevention.***

Decisions regarding use should be made by physicians, in consultation with their patients and, as needed, an expert in the use of antiretroviral drugs. To help guide these discussions, the PHS report provides physicians a summary of available data and outlines factors that should be considered before prescribing therapy. The following factors should be evaluated in considering the potential benefit of therapy:

- Is there convincing evidence that the reported source of exposure is infected? Is the HIV-status of the source known?
- Is there a high risk of transmission from the exposure reported? This depends

on the specifics of the risk event (e.g. no condom, torn condom, type of sex, receptive or insertive partner, injection before or after others, number of people sharing injection equipment) and the presence or absence of factors that would modify risk (e.g. vaginal or anal tears, bleeding, visible genital ulcers or other evidence of an active STD, bleach treatment of injection equipment).

- How much time has elapsed between exposure and presentation for medical care? While the interval during which post-exposure antiretroviral therapy for non-occupational exposure can be beneficial in humans is unknown, animal studies suggest that the therapy is most effective when started within 1-2 hours of exposure and is probably not effective when started later than 24-36 hours after exposure.
- What is the frequency of this type of exposure? Antiretroviral treatment should not be used for repeated exposures.

Potential benefits must be weighed against the risks of drug toxicity, the difficulty of compliance with the regimen, and the potential for individuals at risk to abandon more effective prevention strategies. Because post-exposure is an experimental therapy of unproven efficacy, it should only be prescribed with the informed consent of the patient, after explanation of the potential benefits and risks. Antiretroviral therapy should never be used routinely and should not be used when there is a low risk of transmission or when people seek care too late to anticipate an interruption in transmission.

The report also requests that physicians notify CDC of all cases in which post-exposure therapy is prescribed for nonoccupational exposures. Data collected through the CDC reporting system on the utilization, effectiveness, and toxicity of this therapy may provide the information needed to refine future recommendations.

Primary conclusions of the report include:

- Physicians and individuals at risk for HIV infection should remember that the most effective methods for preventing HIV remain those that prevent exposure to HIV in the first place. Attempting to prevent HIV infection by taking post-exposure antiretroviral therapy should never take the place of adopting and maintaining behaviors that prevent HIV exposure. These include sexual abstinence, having sex only with an uninfected partner, consistent condom use, abstinence from injection drug use, and consistent use of clean equipment for those who are unable to cease injection drug use.
- There are no human data on the effectiveness of post-exposure therapy in reducing HIV infection following sexual or drug-related exposures. While some animal studies suggest potential benefits of its use, it is not known how applicable these data are for humans.
- We do know that the therapy is not 100% effective. Even under ideal

circumstances following an occupational exposure in a health care setting, where treatment is typically started within hours and can be closely monitored, infection has occurred despite therapy.

- There is no such thing as a “morning after pill” to prevent HIV infection. Post-exposure antiretroviral therapy involves multiple drugs, taken several times a day, for at least 30 days. This is an extremely difficult and expensive regimen which can have severe side effects and costs \$600 to \$1000.
- Adherence to the regimen is critical, both to provide the best chance of effectiveness and to prevent the emergence of drug-resistant HIV. Several studies indicate that adherence to this lengthy regimen is difficult. Among rape victims in New York City, for example, only 16% of patients are known to have completed the regimen as prescribed. Among health care workers in the United States, just over 60% complete the regimen. Many report stopping the regimen because of side effects.
- If individuals at risk rely on this less effective strategy instead of maintaining consistently safe behaviors, they may be placing themselves in significant danger. Post-exposure therapy should never be considered a form of primary HIV prevention.

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